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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,075	06/22/2005	Mario Rottlander	421-US-PCT	2734

45821 7590 09/11/2007
LUNDBECK RESEARCH USA, INC.
ATTENTION: STEPHEN G. KALINCHAK, LEGAL
215 COLLEGE ROAD
PARAMUS, NJ 07652

EXAMINER

SHIAO, REI TSANG

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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09/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/540,075

Applicant(s)

ROTTLANDER ET AL.

Examiner

Rei-tsang Shiao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 13, 15-19 and 26-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10, 12, 13 and 17-19 is/are allowed.
- 6) ☒ Claim(s) 26-32 is/are rejected.
- 7) ☒ Claim(s) 15 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/29/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application claims benefit of the foreign application: DENMARK PA200202012 with a filing date 12/27/2002.
2. Amendment of claims 1, 15-16, 18 and 26, cancellation of claims 11, 14 and 20-25 in the amendment filed on June 29, 2007 is acknowledged. Claims 1-10, 12-13, 15-19 and 26-32 are pending in the application.

Information Disclosure Statement

3. Applicant's Information Disclosure Statement, filed on July 29, 2007 has been considered. Please refer to Applicant's copy of the 1449 submitted herein.

Responses to Amendment/Arguments

4. Applicant's arguments regarding the rejection of claims 26-32 under 35 U.S.C. 112, first paragraph have been fully considered and they are persuasive, in part. The nature of the invention of claims 26-32 is drawn to intent methods of use using compounds of formula (I) for treating seizure disorder, a neuropathic pain disorder, a migraine pain disorder, an anxiety disorder, a neurogenerative disorder and a neuronal hyperexcitation state without limitation (i.e., no named diseases).

The state of the prior art is that the pharmacological art involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific diseases by what mechanism). There is no absolute predictability even in view of the seemingly high level of skill in the

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art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic or preventive regimen on its face. Passmore et al. publication (i.e., abstract) disclose KCNQ channel blocker (i.e., linopirdine) for treating pain. Gribkoff publication (i.e., abstract) disclose KCNQ channel blocker for treating seizure or epilepsies.

The only direction or guidance present in the instant specification is the listing of exemplary animal test of maximum electroshock or pilocarpine induced seizures, *in vivo*, see page 71-72 of the specification. There are no *in vitro* or *in vivo* working examples present directly for the treatment of any neurogenerative disorders (i.e., Alzheimer's disease or Huntington's disease) by the administration of the instant invention. Alzheimer's disease has been shown to increase the production and/or deposition of beta-amyloid protein in the brain, see Selkoe publication (i.e., abstract). Rostock et al. US 5,852,053 disclose distinct invention using aminobenzene compounds as NMDA (N-methyl-D-aspartate) receptor antagonists for treating multiple sclerosis. It is noted that Rostock et al. compounds are not agents as the instant KCNQ channel blockers. On the other hand, Duloxetine is a potent inhibitor of neuronal serotonin and norepinephrine reuptake, and Duloxetine is not an agent as the instant KCNQ channel blocker either.

The breadth of the claims is methods of use of the instant compounds effective to "seizure disorder, a neuropathic pain disorder, a migraine pain disorder, an anxiety disorder, a neurogenerative disorder and a neuronal hyperexcitation state" without limitation (i.e., no named diseases). Furthermore, the instant claims cover "seizure

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disorder, a neuropathic pain disorder, a migraine pain disorder, an anxiety disorder, a neurogenerative disorder and a neuronal hyperexcitation state" that are known to exist and those that may be discovered in the future, for which there is no enablement provided. Moreover, there is no reasonable basis for assuming the instant compounds of formula (I) embraced by the claims will share the same physiological properties.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instantly claimed methods. In view of the breadth of the claim, the chemical nature of the invention, and the lack of working examples regarding the activity of the claimed compounds in regards to the treatment of the many disorders resulting from "seizure disorder, a neuropathic pain disorder, a migraine pain disorder, an anxiety disorder, a neurogenerative disorder and a neuronal hyperexcitation state" without limitation, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001, states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue

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experimentation, with no assurance of success. This rejection can be overcome by deleting the limitation "disorder" of seizure disorder, a neuropathic pain disorder, a migraine pain disorder, an anxiety disorder, and by deleting the limitation "neurogenerative disorder and a neuronal hyperexcitation state" (i.e., Alzheimer's disease, Huntington's disease, or Parkinson's disease, etc.) of claim 26-32 respectively, would obviate the rejection. Since claim 20 has been cancelled, the rejection of claim 20 under 35 U.S.C. 112, first paragraph have been obviated herein.

5. Claims 1-10, 12-13, 17-19 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable.

Claim Objections

6. Claims 15-16 are objected to because of the following informalities: the term "as defined above", i.e., see line 3 of claim 15. Replacement of the term "as defined above" with the term "as define in claim 1" would obviate the objection.

7. This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

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If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Rei-tsang Shiao, Ph.D.
Patent Examiner
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September 05, 2007